

AMENDMENT AND RESPONSE TO OFFICE ACTION

Amendment

In the Claims

1. (Currently amended) A vaginal or rectal applicator for transvaginal drug delivery comprising

(a) an applicator barrel, wherein the applicator barrel has a size and shape suitable for insertion into the vagina or rectum and, suitable for preventing penetration of the vaginal wall [[,]] or cervix or rectum, and delivering a pharmaceutical composition to the upper vaginal vault, wherein the applicator barrel comprises a medication chamber at the proximal end of the applicator,

wherein the medication chamber has a smaller diameter than the inner diameter of the applicator barrel and defines a cavity within the applicator barrel having a volume of 1 mL or less, wherein the medication chamber is designed to contain up to 1 mL 1 mL or less of [[a]] the pharmaceutical composition in a form selected from the group consisting of powder, gel, cream, and lotion, wherein the proximal end of the applicator contains an opening suitable for filling the medication chamber with the pharmaceutical composition and dispensing the pharmaceutical composition from the medication chamber, wherein the medication chamber comprises a dispensing end that cannot extend past the proximal end of the applicator barrel, and wherein the applicator barrel comprises a barrier proximal to the opening;

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(b) a plunger, wherein the plunger is insertable in telescoping relation to the applicator barrel until the plunger reaches the barrier; wherein the proximal end of the plunger comprises
(c) a plunger tip, ~~wherein the plunger tip is at the end of the plunger;~~
(c) a flange at the distal end of the applicator; and
(d) an applicator cap, wherein the applicator cap is removable from the proximal end of the applicator barrel.

Claim 2. (Canceled)

3. (Previously presented) The vaginal or rectal applicator of claim 1, wherein the applicator cap has a diameter that is effective at preventing insertion of the vaginal applicator into a vagina when the applicator cap is attached to the applicator barrel.

4. (Original) The vaginal or rectal applicator of claim 1, wherein the applicator cap forms an air-tight seal with the applicator barrel.

5. (Original) The vaginal or rectal applicator of claim 1, wherein the plunger tip forms an air-tight seal with the applicator barrel.

6. (Currently amended) A method of transvaginal ~~or transrectal~~ drug delivery comprising

(1) breech filling a vaginal ~~or rectal~~ applicator with 1 mL or less of a pharmaceutical formulation ~~in a vaginal or rectal applicator~~, wherein the vaginal applicator comprises
(a) an applicator barrel, wherein the applicator barrel has a size and shape suitable for insertion into the vagina ~~or rectum, and suitable for~~ preventing penetration of the

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vaginal wall [[,] or cervix or rectum and delivering the pharmaceutical formulation to the upper vaginal vault, wherein the applicator barrel comprises a medication chamber at the proximal end of the applicator, wherein the medication chamber has a smaller diameter than the inner diameter of the applicator barrel and defines a cavity having a volume of 1 mL or less, wherein the medication chamber comprises a dispensing end that cannot extend past the proximal end of the applicator barrel, wherein the medication chamber is designed to contain up to 1 mL of a pharmaceutical composition and wherein the applicator barrel comprises a barrier proximal to the opening;

(b) a plunger, wherein the plunger is insertable in telescoping relation to the applicator barrel until the plunger reaches the barrier; and (c), wherein the proximal end of the plunger comprises (c) a plunger tip, wherein the plunger tip is at the end of the plunger; and

(c) a flange at the distal end of the applicator;

(2) inserting the applicator barrel into a patient's vagina or rectum, wherein the pharmaceutical formulation is in a form selected from the group consisting of a powder, gel, cream, and lotion, and

(3) depressing the plunger until it reaches the barrier to administer all of the pharmaceutical formulation to the patient's upper vaginal vault.

Claims 7-8. (Canceled).

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9. (Currently amended) The method of claim 6, wherein the pharmaceutical formulation is in an amount effective to treat disorders and diseases of the female urogenital system, cervix, uterus, ovaries, fallopian tubes, and peritoneal cavity, ~~and lower abdominal cavity.~~

Claim 10. (Canceled)

11. (Previously presented) The method of claim 6, further comprising, after step (1) and prior to step (2), placing an applicator cap on the proximal end of the applicator barrel and then removing the applicator cap from the proximal end of the applicator barrel.

12. (New) The applicator of claim 1, wherein the applicator has a rounded tip at the proximal end of the applicator.

13. (New) The method of claim 6, wherein the applicator has a rounded tip at the proximal end of the applicator.